

# HEALTH CARE PROFESSIONAL'S PART D FACT SHEET

*The new Medicare prescription drug program (Part D) is the single biggest change to Medicare in 40 years. Adding a benefit as significant as the new Medicare prescription drug program involves some start-up challenges. The Centers for Medicare & Medicaid Services has taken action to address these issues and make resources available to ensure that you—and your patients—get support. Listed below are steps to make it as easy as possible for you to help your Medicare patients get their medicines.*

## NEW ACTION TO ASSURE A SMOOTH TRANSITION:

Part D transition drug coverage is now extended to March 31, 2006 for those individuals who were enrolled in the first few months of the program. This extra time will help beneficiaries arrange for alternative medication, save more money or allow them to work out a way to continue their current drug if needed. Even after this extension expires, newly enrolled beneficiaries are always entitled to at least a 30-day transitional supply of non-formulary drugs.

## WHAT'S COVERED, WHAT'S NOT:

**Covered:** All plans are required to have formularies that address all medically necessary drugs. Six drug classes of special concern have been specified in which all or substantially all drugs will be on a plan's formulary: anti-neoplastics, anti-HIV/AIDS drugs, immunosuppressants, anti-psychotics, anti-depressants and anti-convulsants. **Not covered:** By law, there are certain types of drugs that Medicare must exclude from Part D: barbiturates; benzodiazepines; drugs used for anorexia, weight loss or weight gain; fertility drugs; drugs used for cosmetic purposes or hair growth; cough and cold medicines; prescription vitamins and minerals, and over-the-counter drugs. For your patients that have both Medicare and Medicaid, check with your state Medicaid program as most programs are continuing to cover all or some of these excluded drugs. Go to: [www.cms.hhs.gov/States/EDC/list.asp#TopOfPage](http://www.cms.hhs.gov/States/EDC/list.asp#TopOfPage) to check which states cover these excluded drugs.

## RESOURCES THAT WILL HELP YOU HELP YOUR PATIENTS:

A **formulary finder** that provides an easy way to access each of the plan's formularies at: <http://formularyfinder.medicare.gov/formularyfinder/selectstate.asp>

**PDP formulary information on the Epocrates website.** This familiar medical software company provides both tier and step therapy information, is updated constantly, and can be easily accessed by computer or downloaded to a PDA at: [www.epocrates.com](http://www.epocrates.com)

**Medicare Prescription Drug Coverage Provider Communication—Request for Prescription Information or Change form** is a general fax form to expedite communications between pharmacists and physicians. [www.cms.hhs.gov/center/provider.asp](http://www.cms.hhs.gov/center/provider.asp)

**Medicare**  
Prescription Drug Coverage 

Clarification about Part B versus Part D drug coverage information and chart found at:

[www.cms.hhs.gov/pharmacy/downloads/partsbdcverageissues.pdf](http://www.cms.hhs.gov/pharmacy/downloads/partsbdcverageissues.pdf)

If your patients forget the plan they joined or still need to select a plan, go to [www.medicare.gov](http://www.medicare.gov) and select the personal plan finder. Enter their Medicare information. If they have joined, it will display the name of the plan. If not, they can call 1-800-MEDICARE (1-800-633-4227) to get help joining.

**Dedicated help for physicians.** E-mail us at [PRIT@cms.hhs.gov](mailto:PRIT@cms.hhs.gov) or join the regular conference call at 2 p.m. EST every Tuesday. Call 1-800-619-2457. Pass code: RBDML.

**For personalized assistance** for people with Medicare, call 1-800-MEDICARE. Phone lines are open 24/7.

**For help on enrollment information** encourage your patients to call 1-800-MEDICARE, go to [www.medicare.gov](http://www.medicare.gov) to access the plan finder, or go to [www.eldercare.gov](http://www.eldercare.gov) to get information about local organizations that can help your patients with personalized counseling. If your patients have low incomes or limited assets and need additional financial help, encourage them to call the Social Security Administration at 1-800-772-1213 or go to [www.socialsecurity.gov/prescriptionhelp](http://www.socialsecurity.gov/prescriptionhelp) to fill out an application.

## GLOSSARY OF COMMON TERMS:

- **Coverage determinations:** The first decision made by a plan regarding the prescription drug benefits an enrollee may be entitled to receive, including a decision not to provide or pay for a Part D drug, a decision concerning an exception request or a decision on the amount of cost sharing for a drug.
- **Exceptions:** A type of coverage determination request. Through the exceptions process an enrollee can request an off-formulary drug, an exception to the plan's tiered cost sharing structure, and an exception to the application of a cost utilization management tool (e.g., step therapy requirement, dose restriction, or prior authorization requirement).
- **Appeals:** The process by which an enrollee may challenge a plan's coverage determination. There are five levels in the appeals process: redetermination by the plan, reconsideration by the Part D QIC (an independent review entity) an ALJ hearing, review by the Medicare Appeals Council and review by a federal district court. We expect most appeals to be resolved at the first two levels.

## **PRESCRIBING PHYSICIAN'S ROLE IN COVERAGE DETERMINATION, EXCEPTIONS AND APPEALS PROCESSES:**

### **Short Decision Making Timeframes**

CMS has directed every prescription drug plan to respond to requests without delay. Plans must communicate decisions on initial coverage determinations no later than 24 hours after receiving an expedited request, or 72 hours after receiving a standard request. If a prescribing physician requests a coverage determination on behalf of an enrollee, the physician also will receive notice of the decision from the plan. Coverage determinations include decisions on formulary and tiering exception requests. If the plan fails to meet the timeframe, the case goes to an independent review entity under contract with CMS for a decision on the case. The independent review entity is commonly referred to as the Part D qualified independent contractor (Part D QIC).

### **Requests Made by Prescribing Physicians**

A coverage determination can be requested by a Part D plan enrollee, by an appointed representative or the prescribing physician on behalf of the enrollee. A prescribing physician can also request an **expedited redetermination** (first level of appeal) on behalf of the enrollee. Prescribing physicians cannot request a **standard redetermination** (first level of appeal) or a reconsideration (second level of appeal).

### **Prescribing Physician Supporting Statements**

Prescribing physicians have an important role in the exceptions process. Whenever an enrollee requests a formulary or tiering exception, the prescribing physician must provide the Part D

plan with an oral or written statement to support the exception request. Formulary exception requests include requests for exceptions to cost utilization management tools, such as step therapy or dose restrictions. The plan's timeframe for making a decision on an exception request does not begin until the prescribing physician's supporting statement is received by the plan. Anyone can go to our coverage determination site at: [www.cms.hhs.gov/center/provider.asp](http://www.cms.hhs.gov/center/provider.asp) to get contact numbers for the plans to facilitate the submission of the supporting statement.

### **Enrollee's Appeal Rights**

If an enrollee doesn't agree with the initial coverage determination made by the plan, the enrollee has the right to appeal the coverage determination. As noted above, the prescribing physician can ask for an expedited first level appeal (redetermination) on behalf of the enrollee. The following chart describes the steps and the time limits of the process. For expedited redeterminations, a Part D plan must give the enrollee (and prescribing physician involved, as appropriate) notice of its decision no later than 72 hours after receiving the request. Decisions on standard redeterminations must be communicated to the enrollee in writing no later than 7 days after receiving the request. If a plan issues an adverse redetermination, the enrollee will receive a notice that includes information on how to request a reconsideration by the Part D QIC.

### **Medicare Prescription Drug Coverage: How to File a Complaint, Coverage Determination or Appeal**

[www.medicare.gov/Publications/Pubs/pdf/11112.pdf](http://www.medicare.gov/Publications/Pubs/pdf/11112.pdf)

### **CMS Part D Appeals Process**

#### **Coverage Determination**

#### **Request for a Coverage Determination\***

Call the plan's number for exceptions by going to:  
[www.cms.hhs.gov/center/provider.asp](http://www.cms.hhs.gov/center/provider.asp)

#### **Standard Process 72 hour time limit\*\***

#### **Expedited Process 24 hour time limit\*\***

#### **First Level of Appeal**

60 days to file a request for a redetermination

#### **Redetermination 7 day time limit**

#### **Redetermination 72 hour time limit**

#### **Second Level of Appeal**

60 days to file a request for reconsideration

#### **Part D QIC Reconsideration 7 day time limit**

#### **Part D QIC Reconsideration 72 hour time limit**

For PDP enrollees: Maximus  
1040 First Avenue  
Suite 200  
King of Prussia, PA, 19406  
Fax: 484-688-5601

Additional appeal rights

\*A request for a coverage determination includes a request for a tiering exception or a formulary exception. A request for a coverage determination may be filed by the enrollee, the enrollee's appointed representative or the enrollee's physician.

\*\*The adjudication timeframes generally begin when the request is received by the plan sponsor. However, if the request involves an exception request, the adjudication timeframe begins when the plan sponsor receives the physician's supporting statement.



## What drugs do Medicare Drug Plans Cover?

Medicare drug plans must cover prescription drugs in all prescribed categories and classes but Medicare drug plans don't have to cover every drug. Certain drugs may be excluded\*. Although your drug plan may not have a specific drug on their list of covered drugs (formulary), a similar drug that is safe and effective should be available. This may be in the form of a therapeutic alternative or generic drug (see below). This makes sure that people with different medical conditions can get the treatment they need.

All Medicare drug plans have negotiated to get lower prices for the drugs on their lists of covered drugs. This means using drugs on your plan's list will save you money. You will pay these lower prices for your prescriptions even before you meet the deductible. In addition, choosing a generic alternative instead of a brand-name drug can save you money with each refill.

### **My drug plan covers generic drugs. Are they as good as brand-name drugs?**

Yes. Today, almost half of all prescriptions in the United States are filled with generic drugs. The U.S. Food and Drug Administration ensures that a generic drug is the same as a brand-name drug in dosage, safety, strength, quality, the way it works, the way it is taken, and the way it should be used. Generic drugs use the same active ingredients as brand-name drugs and work the same way. This means they have the same risks and benefits as the brand-name drugs.

Creating a drug costs a lot of money. Since generic drug makers don't develop a drug from scratch, the costs to bring the drug to market are less. But they must show that their product performs in the same way as the brand-name drug.



## **My drug plan says I need prior authorization for a medicine that is on the plan's list of covered drugs. What does prior authorization mean?**

Medicare drug plans may have rules that require prior authorization. Prior authorization means before a plan will cover certain prescriptions, your doctor must first contact the plan. Your doctor has to show there is a medical reason why you must use that particular drug to treat your condition. Plans do this to be sure certain drugs are used correctly and only when necessary.

## **What is Step Therapy?**

One form of prior authorization is step therapy. With step therapy, in most cases, you must first try certain less expensive drugs that have been proven effective for most people with your condition. For instance, some plans may require you to try a generic drug (if available), then a less expensive brand-name drug that is on their drug list, before you can get a similar, more expensive brand-name drug covered.

However, if you have already tried the similar, less expensive drugs and they didn't work, or if your doctor believes that because of your medical condition you must take the more expensive drug, he or she can contact your drug plan to request an exception. If your doctor's request is approved, the plan will cover the more expensive drug.

## **What if I'm taking a drug that's not on my plan's list (or is a step-therapy drug) when my drug plan coverage takes effect?**

Medicare requires drug plans to fill your prescriptions through March 31, 2006, even if the prescription is for a drug that's not on the plan's drug list (or is a step-therapy drug). This "transition plan" gives you and your doctor time to find another drug on the plan's drug list that would work as well. However, if you have already tried similar drugs and they didn't work, or if your doctor believes that because of your medical condition it is necessary for you to take a certain drug, he or she can contact your plan to request an exception. If your doctor's request is approved, the plan will cover the drug.

## **What are Quantity Limits?**

For safety and cost reasons, plans may limit the quantity of drugs that they cover over a certain period of time. For example, you may be prescribed a drug with the instruction to take one tablet per day. In this instance, a plan may cover only a 30-day supply at a time (up to 90-day supply if filled through a plan's mail order program). If you disagree with the quantity of drugs your plan will cover over a certain period of time, you may ask your plan for an exception.



## What if I choose a drug plan and then my doctor changes my prescription?

If your doctor needs to change your prescription or prescribe a new drug, your plan's list of covered drugs will include drugs to treat your new medical needs. This list and the prices for drugs can change. To get information about the specific drugs your plan covers and their cost, look at the company's website or call the drug plan's customer service number. Your doctor can also get information about the drug list for your plan.

Medicare drug plans cover both generic and brand-name prescription drugs in all prescribed categories and classes. Certain drugs may be excluded\*. Medicare requires drug plans to cover medically necessary drugs, so in general there will be a drug on the plan's list that is safe and effective to treat your condition.

## What if I don't want to switch to another drug?

If your doctor needs to prescribe a drug that isn't on your Medicare drug plan's drug list, and you don't have any other health insurance that covers outpatient prescription drugs, you can request an exception (see below) from your plan. If your plan still won't cover a specific drug you want to use, you may appeal the decision. Urgent appeals take only a few days.

## How do I get an exception?

The first step in requesting an exception is to contact your drug plan. Your plan will tell you how to submit the information they need to make a decision. The plan may request the information in writing. They also can choose to accept the information over the phone. Your doctor must submit a statement supporting your request. The doctor's statement must say that the requested drug is "medically necessary" for treating your condition. Once this information is submitted, your drug plan must notify you of its decision no later than 24 or 72 hours.

## What if the plan decides not to give me an exception?

If your request is denied, you can appeal your drug plan's denial. There are several **levels** of appeal available to you.

### **Appeal through your plan.**

You must request this appeal within 60 calendar days from the date of the plan's first decision. You or your appointed representative must file a standard request in writing unless your plan accepts requests by telephone.





## What if the plan decides not to give me an exception? (continued)

### **Review by an independent review entity.**

If the plan again decides against you, you can request a review by an independent review entity. You or your appointed representative must make a standard or expedited request within 60 days from the date of the decision.

If the independent review entity agrees with your plan's decision, you can still appeal through other levels. These include possible reviews by administrative law judges, a Medicare Appeals Council, and Federal court. Time and dollar limits may apply. More information about these appeals is available on [www.medicare.gov](http://www.medicare.gov) on the web. Or, contact your drug plan for information on their exception and appeals process.

## Someone told me I should switch to another drug plan that covers the prescription I need. Should I?

Medicare drug plans must continue their transition plan through March 31, 2006. The purpose of the 90-day transition period is that if you enrolled in the first few months of the program, you have time to work with your doctor and find a drug that would work as well for you on your plan's drug list. And, if you have already tried similar drugs and they didn't work, or if your doctor believes that because of your medical condition it's necessary for you to take a certain drug, he or she can contact your plan to request an exception. If your doctor's request is approved, the plan will cover the drug.

If you enroll in a Medicare drug plan after March 31, 2006, Medicare requires drug plans to fill your prescriptions once, within the first 30 days your coverage is in effect, even if the prescription is for a drug that's not on the plan's drug list (or is a step-therapy drug). This gives you and your doctor time to find another drug on the plan's drug list that would work as well or time for your doctor to request an exception due to any special medical needs you have for a specific drug. If your doctor's request is approved, the plan will cover the drug.

## For more information

- Talk to your doctor about getting safe and effective alternative drugs that may also save you money, or to request an exception if necessary for your condition.
- Contact your drug plan with questions about what is covered by your plan.
- Call your State Health Insurance Assistance Program for help with an appeal or choosing Medicare prescription drug coverage that meets your needs. Call 1-800-MEDICARE (1-800-633-4227) for their telephone number. TTY users should call 1-877-486-2048.

\* Certain drugs may be excluded by law, such as benzodiazepines, barbiturates, drugs for weight loss or gain, and drugs for relief of colds. Medicare may not pay for these drugs.



## ¿Qué medicamentos cubren los planes de Medicare de recetas médicas?

Los planes de Medicare de recetas médicas deben cubrir medicamentos de todas las categorías y clases recetadas, pero no tienen la obligación de cubrirlos a todos. Ciertos medicamentos pueden estar excluidos\*. A pesar de que su plan puede no tener un medicamento específico en su lista de medicinas cubiertas (formulario), debe tener un medicamento similar que es eficaz y seguro. Esto puede que sea un medicamento genérico o una alternativa terapéutica (ver abajo). Con esto se garantiza que las personas con condiciones médicas distintas puedan obtener el tratamiento que necesitan.

Todos los planes de recetas médicas de Medicare han negociado precios rebajados para los medicamentos que ofrecen en su lista. Lo que significa que si usa los medicamentos de la lista del plan ahorrará dinero. Usted pagará estos precios de descuento aun si todavía no ha pagado el total del deducible. Además, si escoge la alternativa genérica en vez del medicamento de marca puede ahorrar en cada receta.

### **Mi plan de recetas médicas cubre los medicamentos genéricos. ¿Son tan buenos como los de marca?**

Sí. Hoy en día, casi la mitad de las recetas en los Estados Unidos se venden en su alternativa genérica. La Administración de Drogas y Alimentos de los EE.UU. se asegura que un medicamento genérico sea igual al de marca en cuanto a la dosis, seguridad, potencia, calidad, el modo en que funciona, el modo en que debe tomarse y cómo debe ser usado. Los medicamentos genéricos usan los mismos ingredientes activos que los de marca y trabajan del mismo modo. Esto significa que tienen los mismos riesgos y beneficios que los medicamentos de marca.

El desarrollo de los medicamentos es muy costoso. Dado que los fabricantes de los medicamentos genéricos no deben producirlos desde la materia prima, los costos de poner los medicamentos en el mercado son menores. Sin embargo, deben demostrar que el producto funciona igual que los medicamentos de marca.



## **Mi plan de recetas médicas estipula que necesito una autorización previa para un medicamento de la lista del plan. ¿Qué es una autorización previa?**

Los planes de Medicare de recetas médicas pueden tener normas que requieran dicha autorización. Lo que significa que antes de que el plan cubra ciertas recetas, su médico debe primero comunicarse con el plan. Su médico debe demostrar que hay un motivo médico por el cual usted debe usar un medicamento específico para su tratamiento. Los planes ponen este requisito para asegurarse que ciertos medicamentos sean usados correctamente y solo cuando sea necesario.

## **¿Qué es la terapia en pasos/etapas?**

Es un modo de autorización previa. En la terapia en pasos, generalmente, primero deben usar medicinas de menor costo que han sido efectivas en el tratamiento de pacientes que tienen su misma condición. Por ejemplo, algunos planes puede tener como requisito que primero intente con el medicamento genérico (si lo hubiese disponible), luego con la versión más económica del medicamento de marca de su lista, antes de usar el medicamento de marca más caro que esté cubierto por el plan.

Sin embargo, si usted ya intentó con medicamentos similares más baratos y no funcionaron, o si su médico piensa que por su condición médica debe tomar el medicamento más caro, puede comunicarse con el plan y solicitar una excepción. Si el pedido de excepción de su médico es aprobado, el plan cubrirá el medicamento más caro.

## **¿Qué ocurre si estoy tomando un medicamento que no está en la lista del plan (o en la terapia de pasos) cuando la cobertura del plan entra en vigencia?**

Medicare obliga a los planes a cubrir sus recetas hasta el 31 de marzo de 2006, inclusive si el medicamento que usted toma no está en la lista (o en la terapia de pasos). Este “plan de transición” le brinda a usted y a su médico el tiempo para encontrar otro medicamento de la lista del plan que funcione como el que tomaba. Sin embargo, si usted ya intentó con medicamentos similares y no funcionaron, o si su médico piensa que por su condición médica debe tomar el medicamento más caro, puede comunicarse con el plan y solicitar una excepción. Si el pedido de excepción de su médico es aprobado, el plan cubrirá el medicamento.

## **¿Qué son los límites de cantidad?**

Por razones de seguridad y costos, los planes pueden limitar la cantidad de medicamentos que cubren en un período determinado de tiempo. Por ejemplo, puede que le receten un medicamento que debe tomar una vez al día. En este caso, el plan puede cubrir solo un suministro para 30 días a la vez (y hasta 90 días si se compra a través del programa de pedido por correo). Si usted no está de acuerdo, puede pedirle al plan que haga una excepción.





## ¿Qué ocurre si escojo un plan de recetas médicas y luego mi médico me cambia el medicamento?

Si su médico debe cambiar su receta o le receta un medicamento nuevo, la lista del plan incluirá los medicamentos que traten sus necesidades médicas nuevas. La lista del plan y los precios de los medicamentos pueden cambiar. Para obtener información sobre medicamentos específicos cubiertos por su plan y sus costos, visite el sitio Web del plan o llame al servicio al cliente del plan. Su médico también puede obtener información sobre la lista de su plan.

Los planes de recetas médicas de Medicare cubren los medicamentos genéricos y de marca de todas las categorías y clases recetadas. Ciertos medicamentos pueden estar excluidos\*. Medicare obliga a los planes a cubrir las recetas necesarias por motivos médicos, por lo tanto, habrá un medicamento en la lista del plan que es seguro y eficaz para tratar su condición médica.

## ¿Qué ocurre si no quiero cambiar de medicamento?

Si su médico le receta un medicamento que no está en la lista del plan, y usted no tiene otro seguro que cubra las medicinas para los pacientes ambulatorios, puede solicitar una excepción (ver abajo). Si su plan igual no cubre el medicamento específico que usted desea usar, puede apelar la decisión. Las apelaciones urgentes solo demoran unos pocos días.

## ¿Cómo obtengo una excepción?

El primer paso es comunicarse con su plan. Ellos le dirán cómo presentar la información que necesitan para tomar una decisión. Tal vez el plan le pida la información por escrito, o podrían hacerlo por teléfono. Su médico debe enviar una declaración que corrobore su pedido. La declaración del médico debe indicar que el medicamento es “necesario por razones médicas” para el tratamiento de su condición. Una vez presentada la información, su plan debe notificarle la decisión a más tardar en 24-72 horas.

## ¿Qué ocurre si el plan no me otorga la excepción?

Si su pedido es denegado, puede apelar la decisión. Hay varios niveles de apelación disponibles.

### **Apelación a través del plan.**

Debe apelar dentro de los 60 días a partir del momento en que recibe la primera decisión del plan. Usted o su representante deben enviar una solicitud estándar por escrito, a menos que el plan la acepte por teléfono.

### **Revisión por una entidad independiente.**

Si el plan vuelve a decidir en su contra, usted puede solicitar una revisión por parte de una entidad independiente. Usted o su representante deben enviar una solicitud estándar o acelerada en el plazo de 60 días a partir del momento en que recibe la decisión del plan.



## ¿Qué ocurre si el plan no me otorga la excepción? (continuación)

Si la entidad de revisión independiente está de acuerdo con la decisión de su plan, usted puede seguir apelando a través de otros niveles. Entre ellos, revisiones de un juez administrativo, el Consejo de Apelaciones de Medicare y una corte Federal. Puede que se apliquen límites de tiempo y de cantidad monetaria. Si desea más información sobre las apelaciones, visite [www.medicare.gov](http://www.medicare.gov) por Internet. O, comuníquese con su plan para averiguar sobre su proceso de excepción y apelaciones.

## Alguien me dijo que debería cambiar a otro plan que cubra el medicamento que necesito. ¿Debo hacerlo?

Los planes de Medicare de recetas médicas deben continuar con el “plan de transición” hasta el 31 de marzo de 2006. El propósito de estos 90 días de transición es otorgarle dicho período (los primeros meses del programa) para que hable con su médico para encontrar un medicamento de la lista de su plan que sirva para tratar su condición. Y, si usted ya intentó con medicamentos similares y no funcionaron, o si su médico piensa que por su condición médica debe tomar el medicamento más caro, puede comunicarse con el plan y solicitar una excepción. Si el pedido de excepción de su médico es aprobado, el plan cubrirá el medicamento.

Si usted se inscribe en un plan de Medicare de recetas médicas después del 31 de marzo de 2006, Medicare obliga a los planes a cubrir su medicamento una vez dentro de los primeros 30 días de cobertura, incluso si dicho medicamento no está en la lista del plan (o de la terapia de pasos). Esto le dará tiempo para que busque con su médico otro medicamento de la lista para tratar su problema de salud o para que su médico solicite una excepción para el medicamento que necesita por razones médicas. Si el pedido de excepción de su médico es aprobado, el plan cubrirá el medicamento.

## Si desea más información:

- Hable con su médico sobre los medicamentos alternativos que sean eficaces y seguros, que podrían ahorrarle dinero, o para que si fuese necesario por su condición médica, pida una excepción.
- Comuníquese con su plan para preguntarle qué medicamentos cubre.
- Llame al Programa Estatal de Asistencia sobre Seguros de Salud para obtener ayuda para solicitar una apelación o para escoger un plan de Medicare de recetas médicas que responda a sus necesidades. Si desea el número de teléfono, llame GRATIS al 1-800-MEDICARE (1-800-633-4227). Los usuarios de TTY deberán llamar al 1-877-486-2048

\* Ciertos medicamentos pueden estar excluidos por ley, tales como los barbitúricos, benzodiazepinas (ansiolíticos o hipnóticos), medicamentos para bajar de peso o para los síntomas del resfrío. Puede que Medicare no pague por estos medicamentos.



## Medicare Prescription Drug Coverage: How to File a Complaint, Coverage Determination, or Appeal

Beginning January 1, 2006, Medicare offers insurance coverage for prescription drugs through Medicare drug plans. There are two types of Medicare plans that provide insurance coverage for prescription drugs. There will be prescription drug coverage that is a part of Medicare Advantage Plans and other Medicare Health Plans. There will also be Medicare prescription drug coverage that adds coverage to the Original Medicare Plan and some other Medicare Health Plans.

Medicare drug plans will cover generic and brand-name drugs. Plans may have rules about what drugs are covered in different drug categories. This makes sure people with different medical conditions can get the treatment they need.

Most plans will have a formulary, which is a list of drugs covered by the plan. This list must always meet Medicare's requirements, but it can change when plans get new information. Your plan must let you know at least 60 days before a drug you use is removed from the list or if the costs are changing.



## What if I have a complaint about my plan?

If you have a complaint about your Medicare drug plan that doesn't involve coverage or payment for a drug covered by the Medicare drug plan, you have the right to file a complaint with the plan (called a "grievance"). You should file your complaint within 60 days of the event that led to your complaint. Some examples of why you might file a complaint include the following:

- You believe your plan's customer service hours of operation should be different.
  - You have to wait too long for your prescription.
  - The pharmacy is charging you more than you think you should have to pay.\*
  - The company offering your plan is sending you materials not related to the drug plan that you didn't ask to get.
  - The plan doesn't give you a decision about a coverage determination or first-level appeal within the required timeframe.
  - The plan didn't make a decision and send your case to the independent review entity (IRE) about a coverage determination or first-level appeal within the required timeframe.
  - You disagree with the plan's decision not to grant your request for an expedited coverage determination or first-level appeal.
  - The plan didn't provide the required notices.
  - The plan's notices don't follow Medicare rules.
- \* If you think you were charged too much for a prescription, call the company offering your plan to get the most up-to-date price. If the plan doesn't take care of your complaint, call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.



## What if my plan won't cover a drug I need?

If your pharmacist tells you that your Medicare drug plan won't cover a drug you think should be covered, or it will cover the drug at a higher cost than you think you are required to pay, you have the right to

- request a decision called a “coverage determination” from your plan, or
- pay for the prescription and request that the plan pay you back by requesting a coverage determination, or
- request a coverage determination if your plan requires you to try another drug before it pays for the drug prescribed for you, or there is a limit on the quantity or dose of the drug prescribed for you and you disagree with the limit.

You, your doctor, or your appointed representative can call your plan or write them a letter to request that the plan cover the prescription you need.

**Tip:** Any person you appoint, such as a family member or your doctor may help you request a coverage determination or an appeal. Call your plan to learn how to appoint a representative.

Once your plan has received the request, it has 72 hours (for a standard request for coverage or for a request to pay you back) or 24 hours (for an expedited request for coverage) to notify you of its decision. Your request will be expedited if your plan determines or your doctor tells your plan that your life or health will be seriously jeopardized by waiting for a standard decision.

**Note:** For some types of coverage determinations (called “exceptions”), you will need a supporting statement from your doctor explaining why you need the drug you are requesting. You may need this statement if you are requesting that the plan cover a drug that isn't on its list of covered drugs (formulary) or you want the plan to cover a non-preferred drug at the preferred drug cost. Check with your plan to find out if the supporting statement is required. Once your plan receives the statement, its decision-making time period begins.





## How to Appeal

If the plan decides against you, you can appeal the decision. There are **five levels** of appeal available to you.

**1. Appeal through your plan (called a “redetermination”).** You must request this appeal within 60 calendar days from the date of the coverage determination. You or your appointed representative must file a standard request, in writing, unless your plan accepts requests by telephone. You, your appointed representative, or your doctor can call your plan or write to them for an expedited request. Your request will be expedited if your plan determines or your doctor tells your plan that your life or health will be seriously jeopardized by waiting for a standard decision.

Your plan’s address is in your plan materials. Once your plan receives your request for an appeal, the plan has seven days (for a standard request for coverage or for a request to pay you back) or 72 hours (for an expedited request for coverage) to notify you of its decision.

**2. Review by an independent review entity (called a “reconsideration”).** If the plan again decides against you, you can request a review by an independent review entity (IRE). You or your appointed representative must make a standard or expedited request within 60 days from the date of the decision. The request must be made, in writing, to the IRE. Your request will be expedited if the IRE determines or your doctor tells the IRE that your life or health will be seriously jeopardized by waiting for a standard decision.

Once the request for review has been filed, the IRE has seven days (for a standard request for coverage or for a request to pay you back) or 72 hours (for expedited requests for coverage) to notify you of its decision.



## How to Appeal (continued)

**3. Hearing with an administrative law judge.** If the IRE agrees with your plan's decision, you or your appointed representative can request a hearing with an administrative law judge (ALJ). You must make the request in writing within 60 days from the date of the notice of the IRE decision. You must send your request to the entity specified in the IRE's reconsideration notice. To receive an ALJ hearing, the projected value of your denied coverage must meet a minimum dollar amount (you may be able to combine claims to meet the minimum dollar amount). The IRE's decision will include this amount. Once the request for an ALJ hearing is received, the ALJ generally has 90 days to make a decision.

**4. Review by the Medicare Appeals Council.** If the ALJ agrees with your plan's decision, you or your appointed representative can request a review by the Medicare Appeals Council (MAC). You must make the request to the MAC, in writing, within 60 days from the date of the notice of the ALJ's decision. The MAC generally has 90 days to make a decision after receiving the request for a review.

**5. Review by a Federal court.** If the MAC agrees with your plan's decision, you or your appointed representative can request a review by a Federal court. You must make the request, in writing, within 60 days from the date of the notice of the MAC's decision. You must send your request to the entity specified in the MAC's decision notice. To receive a review by a Federal court, the projected value of your denied coverage must meet a minimum dollar amount. The MAC's decision will include the amount.

**Note:** When you join a Medicare drug plan, the plan will send you information about the plan's appeal procedures. Read the information carefully and keep it where you can find it when you need it. Call your plan if you have questions.



## How can I learn more

- Look at the “Medicare & You 2006” handbook, visit [www.medicare.gov](http://www.medicare.gov) on the web, or call 1-800-MEDICARE (1-800-633-4227) for detailed Medicare drug plan information. TTY users should call 1-877-486-2048.
- Read new Medicare publications that can help you compare drug plans and enroll, such as the tip sheet “Comparing Medicare Prescription Drug Coverage” (CMS Pub No. 11110) and the fact sheet, “New Medicare Prescription Drug Coverage—Who Can Help Me Apply and Enroll?” (CMS Pub No. 11125). You can get copies by calling 1-800-MEDICARE or visiting [www.medicare.gov](http://www.medicare.gov) on the web.
- Call your State Health Insurance Assistance Program (SHIP) for free personalized counseling (check the back cover of your “Medicare & You 2006” handbook for the telephone number in your state).
- Attend Medicare-related events in your community. Look for information about these events in your local newspaper or listen for information on the radio.



## Notes

[illegible]







## **La Nueva Cobertura de Medicare para Recetas Médicas: Como tramitar o presentar una queja formal, determinación de cobertura o apelación.**

Medicare ofrece cobertura para recetas médicas a través de planes Medicare. Hay dos tipos de planes Medicare que proveen cobertura para los medicamentos. Hay una cobertura para medicinas que es una parte de los Planes Medicare Advantage y otros planes de salud Medicare. Además esta disponible una cobertura de recetas medicas que se añade al Plan Original de Medicare y otros planes de salud.

Los planes de Medicamentos de Medicare cubren las medicinas genéricas y de marca. Los planes podrían tener reglas sobre que medicinas cubren en diferentes categorías. Esto garantiza que las personas que padecen de diferentes condiciones médicas obtengan el tratamiento adecuado que necesitan.

Muchos planes tienen un formulario, cual es un listado de los medicamentos cubiertos por el plan. Esta lista siempre debe cumplir con los requisitos de Medicare, pero puede cambiar cuando los planes obtienen nueva información. Su plan debe avisarle, por lo menos, 60 días antes que quiten o remuevan medicamentos de la lista o si cambia los costos.



## ¿Qué pasa si tengo una queja sobre mi plan?

Si usted tiene una queja sobre su plan de medicamentos de Medicare que no incurra o envuelva la cobertura o pago para un medicamento cubierto, usted tiene el derecho a tramitar una queja con el plan (llamada “queja formal”). Debe presentar su queja dentro de los 60 días que lo llevo a tomar esa decisión. Algunos ejemplos del porque quisiera presentarla incluyen lo siguiente:

- Usted cree que las horas de operación del servicio al cliente que ofrece su plan deben ser diferentes.
- Tiene que esperar mucho para una receta.
- La farmacia le cobra más de lo que usted piensa debe ser.\*
- La compañía que ofrece su plan han enviado materiales no relacionados con el plan de medicamentos que usted seleccionó en primer lugar.
- El plan no le envía la decisión sobre una cobertura determinada o el primer nivel de apelación requerido dentro del tiempo establecido o indicado.
- El plan no tomó una decisión y envió su caso al panel de entidad independiente (IRE, por sus sigla en inglés) sobre una determinación de cobertura o primer nivel de apelación dentro del tiempo establecido o indicado.
- Esta en desacuerdo con la decisión del plan en no conceder su petición o solicitud para una determinación de cobertura acelerada o primer nivel de apelación más rápida.
- El plan no proveyó las notificaciones requeridas.
- Las notificaciones del plan no siguen las reglas de Medicare.

\* Si piensa que le cobraron mucho por un medicamento recetado, llame a la compañía que ofrece el plan para conseguir el precio actual de la medicina. Si el plan no responde correctamente a su queja, llame GRATIS al 1-800-MEDICARE (1-800-633-4227). Los usuarios de TTY deben llamar al 1-877-486-2048.



## ¿Qué pasa si mi plan no cubre el medicamento que necesito?

Si su farmacéutico le dice que su plan Medicare para medicinas no cubre un medicamento que usted cree debe ser, o cubrirá dicho medicamento a un costo más alto que el que deba ser y le requieren que pague, tiene el derecho a

- Solicitar una decisión que se llama “determinación de cobertura” de su plan, o
- Pagar por la receta y solicitar que el plan le reembolse a través de una determinación de cobertura.

Usted, su médico o representante legal puede llamar o escribir al plan para solicitar que el plan cubra el medicamento que usted necesita.

**Consejo:** Cualquier persona que usted elija, como un miembro de su familia o su doctor podrá ayudarle a solicitar una determinación de cobertura o una apelación. Llame a su plan para aprender como nombrar un representante.

Una vez que su plan haya recibido la solicitud, tiene 72 horas (para un pedido de cobertura estándar o de reembolso) o 24 horas (para un pedido de cobertura acelerado) para notificarle su decisión. Su pedido se acelerará si el plan determina, o su médico le indica al plan, que su vida o salud corren peligro si tiene que esperar a que se procese el pedido estándar.

**Nota:** Para cierto tipo de determinaciones de cobertura (llamadas “excepciones”), necesitará presentar una declaración de su médico explicando la razón por la que necesita el medicamento por el que está solicitando la cobertura. Usted necesitará esta declaración de su médico si está pidiendo que cubran un medicamento que no está en la lista del plan (formulario) o quiere que el plan cubra un medicamento no preferido al costo de uno preferido. Pregúntele al plan si necesita la declaración del médico. Una vez que su plan la reciba, comienza el período de decisión del plan.



## ¿Cómo Apelar?

Si el plan decide en contra de usted, tiene el derecho de apelar la decisión. Hay 5 categorías/niveles disponibles para apelar.

**1. Apelación a través de su plan (llamada “redeterminación”).** Usted debe apelar dentro de los 60 días de la fecha de decisión. Un pedido estándar debe realizarse por escrito a menos que el plan lo acepte por teléfono. Usted (o su representante designado) debe solicitar una decisión estándar por escrito, a menos que el plan acepte el pedido por teléfono. Usted (su representante o su médico) puede llamar o escribir al plan para solicitarles una decisión acelerada. Se acelerará la decisión si su plan determina o su médico le indica al plan que su vida o su salud corren serio peligro si debe esperar por la decisión estándar.

La dirección del plan la encontrará en los documentos del plan. Una vez que el plan haya recibido su pedido de apelación, tiene siete días (para un pedido estándar de cobertura o de reembolso) o 72 horas (para un pedido de cobertura acelerado) para comunicarle la decisión.

**2. Revisión de una entidad independiente llamada “reconsideración”).** Si el plan se decide nuevamente en su contra, usted puede pedir una revisión por una entidad independiente (IRE por su sigla en inglés). Debe hacer el pedido dentro de los 60 días siguientes a la decisión. El pedido debe hacerse por escrito. Se acelerará la decisión si IRE determina o su médico manifiesta que su vida o su salud corren serio peligro si debe esperar por la decisión estándar.

Una vez que la solicitud haya sido archivada, el IRE tiene 7 días (para solicitudes estándares sobre cobertura o reembolso para pagarle) o 72 horas para notificarle la decisión a usted.



## ¿Cómo Apelar? (continuación)

**3. Audiencia con un juez administrativo.** Si el IRE está de acuerdo con la decisión de su plan, usted (o su representante) puede solicitar una audiencia con un juez administrativo (ALJ por su sigla en inglés). Debe solicitarlo por escrito dentro de los 60 días de la decisión de IRE. Usted debe enviar el pedido de apelación a la entidad especificada en el aviso de reconsideración de IRE. Para que le otorguen la audiencia con un ALJ, el valor proyectado de la cobertura denegada debe ser de una suma mínima (usted podría combinar varios reclamos para alcanzar la cantidad mínima requerida). La decisión de IRE incluirá esta cantidad. Una vez que se haya recibido el pedido de audiencia, el ALJ generalmente tiene 90 días para tomar una decisión.

**4. Revisión del consejo de apelaciones de Medicare.** Si el ALJ está de acuerdo con la decisión de su plan, usted (o su representante designado ) puede solicitar por escrito una revisión del Consejo de Apelaciones de Medicare (MAC por su sigla en inglés), en los 60 días siguientes a que le comuniquen la decisión del ALJ. El MAC por lo general tiene 90 días para tomar una decisión a partir del momento en que recibe el pedido de revisión.

**5. Revisión de una corte federal.** Si el MAC está de acuerdo con la decisión de su plan, usted (o su representante designado) puede solicitar por escrito una revisión de una corte federal, en los 60 días siguientes a que le comuniquen la decisión de MAC. Usted debe enviar el pedido de apelación a la entidad especificada en el aviso de reconsideración de MAC. Para que se la otorguen, el valor proyectado de la cobertura denegada debe ser de una cantidad mínima. La decisión de MAC incluirá esta cantidad.

**Nota:** Cuando se inscribe en un plan Medicare para Medicinas, el plan le enviará información sobre el proceso de apelaciones del plan. Lea dicha información cuidadosamente y guárdela en un lugar donde la pueda encontrar fácilmente. Llame al plan si tiene preguntas.





## **¿Dónde puedo aprender más?**

- Leer el manual de “Medicare y Usted 2006”, acceder [www.medicare.gov](http://www.medicare.gov) por Internet, o llamar GRATIS al 1-800-MEDICARE (1-800-633-4227) para información sobre los detalles de los planes Medicare para medicamentos.
- Llame a su Programa Estatal de Asistencia sobre Seguros de Salud para asesoramiento personalizado y gratis (vea el anverso en la última página del manual “Medicare y Usted 2006” para obtener el número de teléfono en su estado).
- Asistir a eventos locales relacionados con Medicare. Busque información sobre estos eventos en su periódico local o espere a escuchar la información en la radio.



## Notas

[illegible]





## CENTERS FOR MEDICARE & MEDICAID SERVICES



# More Time to Fill the Prescriptions You Need

Medicare and your drug plan are working together to make sure you have coverage for the prescriptions you need.

All Medicare drug plans must make sure that the people in their plan can get medically-necessary drugs to treat their conditions. Medicare drug plans cover both generic and brand-name prescription drugs. The drug lists must include a range of drugs in the prescribed categories and classes. This makes sure that people with different medical conditions can get the treatment they need.

Most plans have a list of drugs covered by the plan called a formulary. Your plan may have a different brand-name drug for your condition on its list than the prescription you currently take. You can work with your doctor to change to this drug or to a generic drug if one is on the list. If your doctor thinks you need a drug that isn't on the list, your doctor can apply for an exception to try to continue your current prescription. If the plan denies the request, you can appeal their decision.

When your Medicare prescription drug coverage starts and you go to the pharmacy for the first time to fill a prescription, you may not have had time to work with your doctor. You may still be taking a prescription that isn't covered by your Medicare drug plan, or a prescription that requires a prior authorization by your doctor before your Medicare drug plan would cover it.

So that you are able to leave the pharmacy with a prescription, your plan will cover a 30-day supply of your current prescription. You need to contact your doctor so you can change your prescription to one that is covered by your plan or if necessary, work on requesting an exception.



Medicare and your plan are now providing you more time to work with your doctor on a solution in these cases. If your Medicare drug plan coverage was effective on January 1 or February 1, 2006, you will now have until March 31, 2006, to work with your doctor to switch to a prescription on your plan's list. Until then, your plan will allow your pharmacist to fill your current prescription through March 31, 2006.

If you join a Medicare drug plan and your coverage starts on March 1, 2006, or later, your plan will still allow you to fill a one-time, 30-day supply of your prescription in these cases. Then, you will have 30 days to talk with your doctor about a change that works for you.





## CENTROS DE SERVICIOS DE MEDICARE Y MEDICAID



# Más Tiempo para Llenar las Recetas Médicas que Necesita

Medicare y su plan para recetas médicas están trabajando en conjunto para asegurar que usted tenga la cobertura de medicamentos que necesita.

Todos los planes de Medicare para recetas médicas deben asegurarse de que las personas en su plan puedan conseguir las medicinas “médicamente-necesarias” para tratar sus condiciones. Los planes de Medicare cubren los medicamentos recetados genéricos y de marca. Las listas de medicamentos deben incluir una gama de medicinas en las categorías y clases más comúnmente prescritas. Esto garantiza que los beneficiarios con diversas condiciones médicas puedan conseguir el tratamiento que necesitan.

La mayoría de los planes tienen una lista de medicinas cubiertas por el plan. La lista de medicamentos cubiertos se conoce como formulario. Su plan puede tener en su lista un medicamento para su condición diferente a la que toma actualmente. Usted puede hablar con su doctor para cambiar esta medicina o a un medicamento genérico si una está en la lista. Si su doctor piensa que necesita una medicina que no está en la lista, su doctor puede solicitar una excepción para intentar continuar su prescripción actual. Si el plan niega la petición, usted puede apelar la decisión.

Cuando su cobertura de Medicare para recetas médicas comienza y va a la farmacia por primera vez para llenar una prescripción, puede que usted no haya tenido tiempo para consultar con su médico. Puede ser que todavía esté usando un medicamento que no sea cubierto por su plan de Medicare, o una prescripción que requiera una autorización previa de su doctor antes de que su plan la cubra.

Su plan cubrirá un suministro de 30 días de su medicamento actual para que pueda salir de la farmacia con su prescripción. Usted necesita comunicarse con su médico para cambiar su medicamento a uno que sea cubierto por su plan o en caso de necesidad, solicitar una excepción.



Medicare y su plan ahora le están proporcionando más tiempo para hablar con su médico y obtener una solución en estos casos. Si su cobertura de Medicare para medicamentos comenzó el 1 de enero o el 1 de febrero de 2006, usted tendrá hasta el 31 de marzo de 2006, para consultar con su médico y cambiar su medicamento a uno que esté en la lista de su plan. Hasta entonces, su plan permitirá que su farmacéutico llene su prescripción actual hasta el 31 de marzo de 2006.

Si usted se inscribe en un plan de Medicare para recetas médicas y su cobertura comienza en o después del 31 de marzo de 2006, su plan le permitirá obtener un suministro de 30 días de su medicamento (una vez solamente) en estos casos. Después, tendrá 30 días para hablar con su médico sobre un cambio que funcione para usted.

## **MEDICARE PRESCRIPTION DRUG COVERAGE AND YOUR RIGHTS**

You **have the right to get a written explanation** from your Medicare drug plan if:

- Your doctor or pharmacist tells you that your Medicare drug plan will not cover a prescription drug in the amount or form prescribed by your doctor.
- You are asked to pay a different cost-sharing amount than you think you are required to pay for a prescription drug.

The Medicare drug plan's written explanation will give you the specific reasons why the prescription drug is not covered and will explain how to request an appeal if you disagree with the drug plan's decision.

You **also have the right to ask** your Medicare drug plan **for an exception** if:

- You believe you need a drug that is not on your drug plan's list of covered drugs. The list of covered drugs is called a "formulary;" or
- You believe you should get a drug you need at a lower cost-sharing amount.

### **What you need to do:**

- Contact your Medicare drug plan to ask for a written explanation about why a prescription is not covered or to ask for an exception if you believe you need a drug that is not on your drug plan's formulary or believe you should get a drug you need at a lower cost-sharing amount.
- Refer to the benefits booklet you received from your Medicare drug plan or call 1-800-MEDICARE to find out how to contact your drug plan.
- When you contact your Medicare drug plan, be ready to tell them:
  1. The prescription drug(s) that you believe you need.
  2. The name of the pharmacy or physician who told you that the prescription drug(s) is not covered.
  3. The date you were told that the prescription drug(s) is not covered.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0975. The time required to distribute this information collection once it has been completed is one minute per response, including the time to select the preprinted form, and hand it to the enrollee. If you have any comments concerning the accuracy of the time estimates or suggestions for improving this form, please write to CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

Form Instructions  
“Medicare Prescription Drug Coverage and Your Rights”  
Pharmacy Notice

CMS-10147

A Medicare Part D plan must provide this notice to its network pharmacies for use in instructing enrollees to contact their Part D plan (Medicare drug plan) to obtain a coverage determination or ask for a formulary or tiering exception if the enrollee disagrees with the information provided by the pharmacist. This notice may be distributed to enrollees or conspicuously posted at the pharmacy. Posted notices must be at least as large as the individual notices that are distributed to enrollees, but larger dimensions and font size are permissible. This notice fulfills the requirements at 42 CFR §423.562(a)(3).

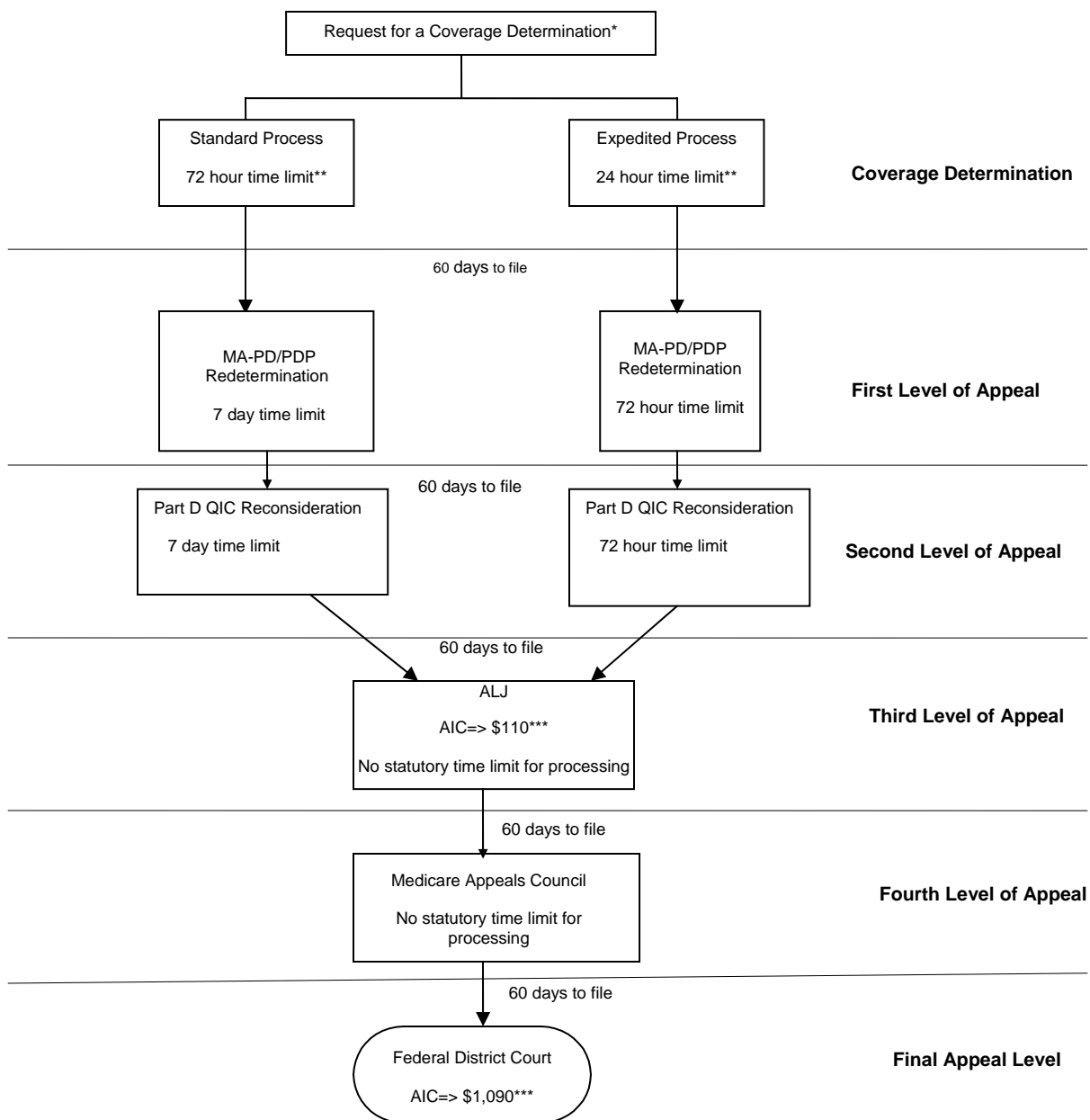
This is a standard notice. Part D plans may not deviate from the content of this notice. Please note that the OMB control number must be displayed in the upper right corner of the notice.

Heading

Logo not required. Pharmacies may elect to place their logo in the space above “Medicare Prescription Drug Coverage and Your Rights.” In addition, a plan may elect to place the “MedicareRx” mark on the notice provided the plan is authorized to use this mark.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0975. The time required to distribute this information collection once it has been completed is one minute per response, including the time to select the preprinted form and hand it to the enrollee. If you have any comments concerning the accuracy of the time estimates or suggestions for improving this form, please write to CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

## Medicare Part D Appeals Process



AIC = Amount in controversy  
 ALJ = Administrative Law Judge  
 IRE = Independent Review Entity  
 MA-PD = Medicare Advantage plan that offers Part D benefits  
 PDP = Prescription Drug Plan

\*A request for a coverage determination includes a request for a tiering exception or a formulary exception. A request for a coverage determination may be filed by the enrollee, the enrollee's appointed representative, or the enrollee's physician.

\*\*The adjudication timeframes generally begin when the request is received by the plan sponsor. However, if the request involves an exception request, the adjudication timeframe begins when the plan sponsor receives the physician's supporting statement.

\*\*\*Starting in 2005, the AIC requirement for an ALJ hearing and Federal District Court will be adjusted in accordance with the medical care component of the consumer price index.

## PART D GRIEVANCES, COVERAGE DETERMINATIONS, AND APPEALS

The process for resolving grievances, coverage determinations, and appeals under the Medicare Part D program is modeled after the Medicare Advantage program.

### Grievances

Any complaint or dispute, other than one involving a coverage determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a plan sponsor.

- Enrollee may file a grievance with the plan orally or in writing.
- Enrollee must file a grievance within 60 days of the event that gives rise to the grievance.
- Enrollee must be notified of the decision no later than 30 days after the plan receives the grievance.
- If the grievance relates to a plan's refusal to expedite a coverage determination, the enrollee must be notified of the decision no later than 24 hours after the plan receives the grievance.

### Coverage Determinations

The initial decision made by, or on behalf of, a Part D plan sponsor regarding payment or benefits to which an enrollee believes he or she is entitled.

An **exception** is a type of coverage determination that is unique to the Part D benefit. An enrollee may request a tiering exception or a formulary exception.

- **Tiering Exception:** Permits enrollees to obtain a non-preferred drug at the cost-sharing amount applicable to drugs on the preferred tier.
- **Formulary Exception:** Ensures that enrollees have access to medically necessary Part D drugs that are not included on a plan's formulary. Also permits enrollees to request an exception to a quantity or dose limit or a requirement that the enrollee try another drug before the plan sponsor will pay for the requested drug.
- Generally, a plan sponsor must grant an exception when the preferred or formulary drug for treatment of the same condition would not be as effective as the prescribed drug, would have adverse effects for the enrollee, or both.
- Plans are prohibited from requiring enrollees to seek additional exception requests for refills.

An enrollee, the enrollee's appointed representative, or the enrollee's prescribing physician may request a coverage determination by the plan sponsor.

A plan sponsor must notify an enrollee of its coverage determination as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving an expedited request, or 72 hours after receiving a standard request.

If a plan does not make a coverage determination within the applicable timeframe, the request must be forwarded to the independent review entity for review

### Appeals

If a Part D plan sponsor makes an adverse coverage determination, the enrollee may request an appeal. There are five levels of appeal available in the following sequence:

- **Redetermination by the Part D plan sponsor**
  - Can make expedited requests orally or in writing; must make standard requests in writing
  - The enrollee must be notified of the decision no later than 72 hours after receiving an expedited request, or 7 days after receiving a standard request

- If a plan does not make a redetermination within the applicable timeframe, the request must be forwarded to the independent review entity for review
- Unfavorable decisions are appealable to the IRE
- Reconsideration by the independent review entity (IRE)
  - Expedited and standard requests must be made in writing
  - The enrollee must be notified of the decision no later than 72 hours after receiving an expedited request, or 7 days after receiving a standard request
  - Unfavorable decisions are appealable to a DHHS Administrative Law Judge (ALJ)
- Hearing with a DHHS ALJ
  - Hearing requests must be in writing; unfavorable ALJ decisions are appealable to the Medicare Appeals Council (MAC)
- Review by the MAC
  - Review requests must be in writing; unfavorable decisions are appealable to federal district court
- Review by a federal district court
  - Enrollee must file a civil action in federal district court





# Medicare<sup>Rx</sup>

Prescription Drug Coverage <sup>Rx</sup>

## **Working with Plan Formularies:** *Transition Supplies, Prior Authorization, Quantity Limits, Step Therapy, Exceptions*

**2006 National Medicare & You Training  
Centers for Medicare & Medicaid Services  
March 2, 2006**

**Panel: Vanessa Duran  
Jeffrey Kelman, MD  
Craig Miner**





# Topics for Today's Discussion

- What you need to know about plan formularies
  - Transition Supplies
  - Prior Authorization
  - Quantity Limits
  - Step Therapy
  - Exceptions






# Plan Formularies

## ■ Medicare drug plans

- Do not cover every drug
- Must cover prescription drugs in all prescribed categories and classes
  - Must include more than one drug in each class
  - Safe and effective similar drug should be available
  - May be generic drug or therapeutic alternative
- Certain drugs are excluded by law
  - Medicare cannot pay for these drugs






# Plan Formularies

- 
- Drug plans negotiate to get lower prices for the drugs on their formularies
  - Using drugs on a plan's list will save money
  - Enrollees will pay lower prices for prescriptions
  - Choosing a generic alternative instead of a brand-name drug can save money with each refill
- 
- 






# Generic Drugs

- 
- Almost half of prescriptions in U.S. filled with generic
  - FDA ensures generic drug is same as brand-name
    - Dosage
    - Safety
    - Strength
    - Quality
    - How it works, is taken, and should be used
  - Generic drugs
    - Use the same active ingredients as the brand-name drugs
    - Work the same way
    - Have the same risks and benefits as the brand-name drugs
- 
- 






# Plan Formularies

- 
- Plans manage formularies using
    - Prior authorization
    - Step therapy
      - Encouraging use of generic drugs
    - Quantity limits
  - Processes available to use
    - Transition supply
    - Exceptions
    - Appeals
- 
- 






# Transition Supply

- 
- Plans must fill prescriptions not on plan's list
    - For new enrollees
    - For residents of long-term care facilities
  - Allows time for member and doctor
    - To find another drug on the plan's formulary
    - To request an exception
      - If person has already tried similar drugs and they didn't work or
      - If doctor believes a certain drug is necessary because of the person's medical condition
      - If the request is approved, the plan will cover the drug
- 
- 





# Transition Supply

- 
- Ensures prescription is filled
  - Supply of current prescription either
    - Not on the plan formulary or
    - Subject to formulary rules
  - Need to contact doctor to
    - Change prescription or
    - Request an exception
- 
- 



# How Transition Works



- Immediate supply provided to new enrollee

If plan effective January 1 through March 1, 2006	Supply of the current prescription until March 31
If plan effective April 1, 2006, or later	Plan will fill one-time, 30-day supply of current prescription

- While using transition supply
  - Work with doctor to switch to drug on plan's list
  - If *medically necessary*, request an exception






# Prior Authorization

- 
- For certain prescriptions, plans may require doctor
    - To contact the plan
    - To show there is a medical reason
      - Ensures drugs are used
        - Correctly
        - Only when medically necessary
- 






# How Prior Authorization Works

- 
- Plans may have rules requiring prior authorization
    - Doctor must first contact the plan
      - To show there is a medical reason why that particular drug must be used
    - Ensures certain drugs are used correctly and only when necessary
  - Prior authorization is also required for specific drugs
    - Could be due to a very specific limited FDA indication
    - Drugs with a potential for misuse or overuse
    - Drugs that should be limited to a maximum quantity based on manufacturer information
- 
- 



# Step Therapy

- 
- One form of prior authorization
  - In most cases, must first try less expensive drugs
    - Proven effective for most people with condition
    - Can request an exception
      - Tried less expensive drug and it didn't work or
      - Doctor believes person must take the more expensive drug for reasons of medical necessity
      - If approved, plan will cover the more expensive drug
- 
- 






# Quantity Limits

- Plans may limit quantity of a drug they cover over a certain time period
  - For safety and cost reasons
  - May ask plan for an exception
    - For reasons of medical necessity






# Requesting an Exception

- 
- Can request an exception from the plan
  - Contact the drug plan—the plan will advise
    - How to submit request
    - What information to submit
    - Doctor must submit supporting statement
    - Must demonstrate requested drug is “medically necessary”
  - After receiving physician’s statement, plan must notify enrollee of its decision within
    - 24 hours (expedited) or
    - 72 hours (standard)
- 
- 








# Tiered Pricing

- 
- Many plans place drugs into different “tiers”
    - To help lower costs
    - Tiers can be formed in different ways
  - Example of how it might work
    - **Tier 1:** Generic drugs—generally cost the least
    - **Tier 2:** Preferred brand-name drugs—cost more than tier 1
    - **Tier 3:** Non-preferred brand-name drugs—cost more than tiers 1 and 2
  - List may not include a person’s specific drug
  - If plan changes its drug list during the year, the plan must notify members of the change
- 
- 





# Tiered Exception

- 
- Obtain a non-preferred drug at the lower cost of drugs in the preferred tier
    - If the preferred drug for treatment
      - Would not be as effective and/or
      - Would have adverse effects
  - When approved
    - Plan must provide coverage at the cost-sharing level that applies for preferred drugs
      - But not at the generic cost-sharing level
      - For the remainder of the plan year
- 
- 






# Formulary Exception

- 
- Gives access to drugs not included on formulary
  - Plans must have procedures to ensure access to drugs not included on formulary
  - Plans determine level of cost sharing
- 




# Appeals



- 
- A person can appeal a Medicare drug plan's unfavorable exception decision
  - First level is appeal to the plan
  - Expedited appeals take only a few days
  - An appointed representative may appeal
  - Generally, must be made in writing
  - Will receive information about appeal procedures upon enrollment
  - Five levels of appeal
- 
- 



# Remember






## ■ Plan ahead

- 
- 
- Don't wait until transition supply is gone
  - Talk with doctor about
    - Prior authorization
    - Switching to covered drug
    - Asking for an exception if medically necessary
  - Contact the drug plan with questions about what is covered by the plan



# For More Information

- 
- Contact drug plan with questions about coverage
  - Talk to doctor
    - About safe and effective alternative drugs
    - To request an exception if necessary
  - Call State Health Insurance Assistance Program (SHIP)
    - Call 1-800-MEDICARE (1-800-633-4227) for SHIP telephone number
    - TTY users should call 1-877-486-2048
  - Providers visit  
[www.cms.hhs.gov/center/provider.asp](http://www.cms.hhs.gov/center/provider.asp)
- 
- 



# Thank you for your attention

- This training will be available after the broadcast at <http://media.cms.hhs.gov/cms/partner03022006.wma>